

Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Special Nutritionals

ARMS#

13187



7 - PROCEDURES

**000001**

PATHOLOGISTS:

## HEMATOLOGY BLOOD CELL COUNTS

COLLECTION DATE 09/12/98  
COLLECTION TIME 1635

**BLOOD CELL COUNT**  
WBC 13.3 H  
RBC 5.40  
HGB 16.3 H  
HCT 47.8  
MCV 88.5  
RDW 13.2  
PLATELET 294

UNITS	REF-THER
10 <sup>9</sup> /L	[3.4-10.7]
10 <sup>12</sup> /	[3.70-5.40]
GM/DL	[11.7-15.8]
%	[33.2-48.0]
FL	[82.0-99.0]
%	[11.0-15.0]
10 <sup>9</sup> /L	[150-400]

**AUTOMATED DIFFERENTIAL PERCENTAGES**  
AUTO GRAN % 90.0 H  
AUTO LYMPH % 7.0 L  
AUTO MONO % 2.1 L  
AUTO EOS% .7  
AUTO BASO% .2

%	REF-THER
%	[40.0-80.0]
%	[10.0-44.0]
%	[4.0-15.0]
%	[.0-8.0]
%	[.0-3.0]

**AUTOMATED DIFFERENTIAL ABSOLUTE**  
GRAN ABS 12.0 H  
LYMPH ABS 0.9  
MONO ABS 0.3  
EOS ABS 0.1  
BASO ABS 0.0

10 <sup>9</sup> /L	REF-THER
10 <sup>9</sup> /L	[1.7-8.5]
10 <sup>9</sup> /L	[0.9-3.6]
10 <sup>9</sup> /L	[0.3-1.0]
10 <sup>9</sup> /L	[0.0-0.6]
10 <sup>9</sup> /L	[0.0-0.3]

## CHEMISTRY ELECTROLYTES

COLLECTION DATE 09/13/98  
COLLECTION TIME 0633

SODIUM 133 L  
POTASSIUM 3.8  
CHLORIDE 102  
CO2 21 L  
ANION GAP 10

UNITS	REF-THER
MM/L	[136-145]
MM/L	[3.4-5.1]
MM/L	[99-110]
MM/L	[22-32]
MM/L	[4-15]

medWatch Report #15187  
Follow-Up Adverse Report  
Thomas S. Donaldson 01-11-99  
Exhibit: 3 page 25 of 48

Memo Date: January 11, 1999  
Subject: F/U Adverse Report  
To: Dorothy L. Olson, ASCSO  
From: Thomas S. Donaldson, CSO  
Exhibit No: page of

### Footnotes

L = Low, H = High

Adm. Date: 09/12/98  
Adm. Doctor:   
Discharge Date: 09/15/98  
Print Date/Time: 09/17/98 0121

\*\* CONTINUE TO NEXT PAGE \*\*

Patient Name:   
Medical Record   
Patient Account   
DOB:   
Age: 56 YRS Sex: F  
Loc:   
Page: 1

DISCHARGE LAB SUMMARY

HEM-CBC/DIFF CHEMISTRY ELECT

000002

PATHOLOGISTS:

### CHEMISTRY-BLOOD CHEMISTRY PROFILES

COLLECTION DATE 09/12/98  
COLLECTION TIME 1635

BILIRUBIN TOTAL .5  
BILI DIRECT .2  
ALBUMIN 4.1  
ALK PHOS 74  
ALT 38  
AST 60 H

UNITS REF-THER  
MG/DL [.1-1.2]  
MG/DL [.0-.5]  
GM/DL [3.5-5.0]  
U/L [25-125]  
U/L [0-40]  
U/L [10-40]

09/12/98 1635

RESULTS CALLED TO [REDACTED] IN [REDACTED] AT 09/12/98 17:31 BY [REDACTED]

### CHEMISTRY - LIPID STUDIES

PROCEDURE TRIGLYCER  
UNITS MG/DL  
REF-THER (10-190)  
14SEP98 MON 0555 105

medWatch Report #13187  
Follow-Up Adverse Report  
Thomas S. Donaldson 01-11-99  
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Memo Date: January 11, 1999  
Subject: F/U Adverse Report  
To: Dorothy L. Olson, ASCSQ  
From: Thomas S. Donaldson, CSQ, ASD  
Exhibit No: page of

#### Footnotes

H = High

Adm. Date: 09/12/98  
Adm. Doctor: [REDACTED]  
Discharge Date: 09/15/98  
Print Date/Time: 09/17/98 0121

\*\* CONTINUE TO NEXT PAGE \*\*

Patient Name: [REDACTED]  
Medical Record #: [REDACTED]  
Patient Account #: [REDACTED]  
DOB: [REDACTED] Age: 56 YRS Sex: F  
Loc: [REDACTED] Page: 3

DISCHARGE LAB SUMMARY

BCP-BLD CHEM PR LIPID STUDIES

000003

PATHOLOGISTS:

### CHEMISTRY ROUTINE

PROCEDURE UNITS REF-THER	GLUCOSE F MGS/DL (70-110)	CALCIUM MG/DL (8.5-10.5)	ALBUMIN GM/DL (3.5-5.0)
13SEP98 SUN 0630	197 H	8.4 L	
15SEP98 TUE 0628	145 H	8.6	3.0 L

### CHEMISTRY ENZYMES

#### HEPATIC ENZYMES

PROCEDURE UNITS REF-THER	AST U/L (10-40)
13SEP98 SUN 0633	21

CRITICAL NOT CALLED. SIMILAR TO PREVIOUS RESULTS.

#### MISCELLANEOUS ENZYMES

PROCEDURE UNITS REF-THER	AMYLASE SERUM U/L (17-115)
15SEP98 TUE 0628	186 H
14SEP98 MON 0555	605 C

CRITICAL RESULTS WERE CALLED TO [REDACTED] ON [REDACTED] BY TECH [REDACTED];  
DATE&TIME: 09/14/98 08:05\_.

13SEP98 SUN 0633	1101 C
12SEP98 SAT 1635	1296 C

medWatch Report #13187  
Follow-Up Adverse Report [REDACTED]  
Thomas S. Donaldson 01-11-99  
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Memo Date: January 11, 1999  
Subject: F/U Adverse Report [REDACTED]  
To: Dorothy L. Olson, ASCSO  
From: Thomas S. Donaldson, CSO [REDACTED]  
Exhibit No: page of [REDACTED]

#### Footnotes

L = Low, H = High, C = Critical

\*\* CONTINUE TO NEXT PAGE \*\*

Adm. Date: 09/12/98  
Adm. Doctor: [REDACTED]  
Discharge Date: 09/15/98  
Print Date/Time: 09/17/98 0121

Patient Name: [REDACTED]  
Medical Record #: [REDACTED]  
Patient Account #: [REDACTED]  
DOB: [REDACTED] Age: 56 YRS Sex: F  
Loc: [REDACTED] Page: 2

DISCHARGE LAB SUMMARY

ROUTINE CHEMIST CHEMISTRY ENZYM

000004

PATHOLOGISTS:

REFERENCE LAB MISC.

HEMOGLOBIN A1C

DATE/TIME DRAWN 09/15/98 0628 ACC#

HEMOGLOBIN A1C = 6.1% (H)  
(NORMAL = 4-6%)

Correlation with HgA1C and Glucose control is as follows:

HGA1C RESULT	AVERAGE BLOOD GLUCOSE (MG/DL)
6	120
7	155
8	190
9	225
10	260
11	295
12	330
13	365

Every sustained decrease in HGA1C of 1 percent results in a 25 percent decrease in the risk of developing diabetic microvascular complications.

medWatch Report #13187  
Follow-Up Adverse Report  
Thomas S. Donaldson 01-11-99  
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Memo Date: January 11, 1999  
Subject: F/U Adverse Report  
To: Dorothy L. Olson, ASCSO  
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Exhibit No: page of

@ = HEMOGLOBIN A1C Performed at

\*\*\*\*\* END OF CHART \*\*\*\*\*

Adm. Date: 09/12/98

Adm. Doctor:

Discharge Date: 09/15/98

Print Date/Time: 09/17/98 0121

Patient Name:

Medical Record #

Patient Account

DOB:

Age: 56 YRS

Sex: F

Loc:

Page: 4

DISCHARGE LAB SUMMARY

REF LAB CHEMIST

000005

**ROUTINE RECORD**

Med: [REDACTED]

**Confirmed by:**

medWatch Report #13187

Follow-Up Adverse Report *AP*  
Thomas S. Donaldson 01-11-99  
Exhibit: 3 page 15 of 48

Memo Date: January 11, 1999

Subject: ~~F/U Adverse Report~~

To: ~~Dorothy L. Olson, ASCSO~~

From: Thomas S. Donaldson, Esq.

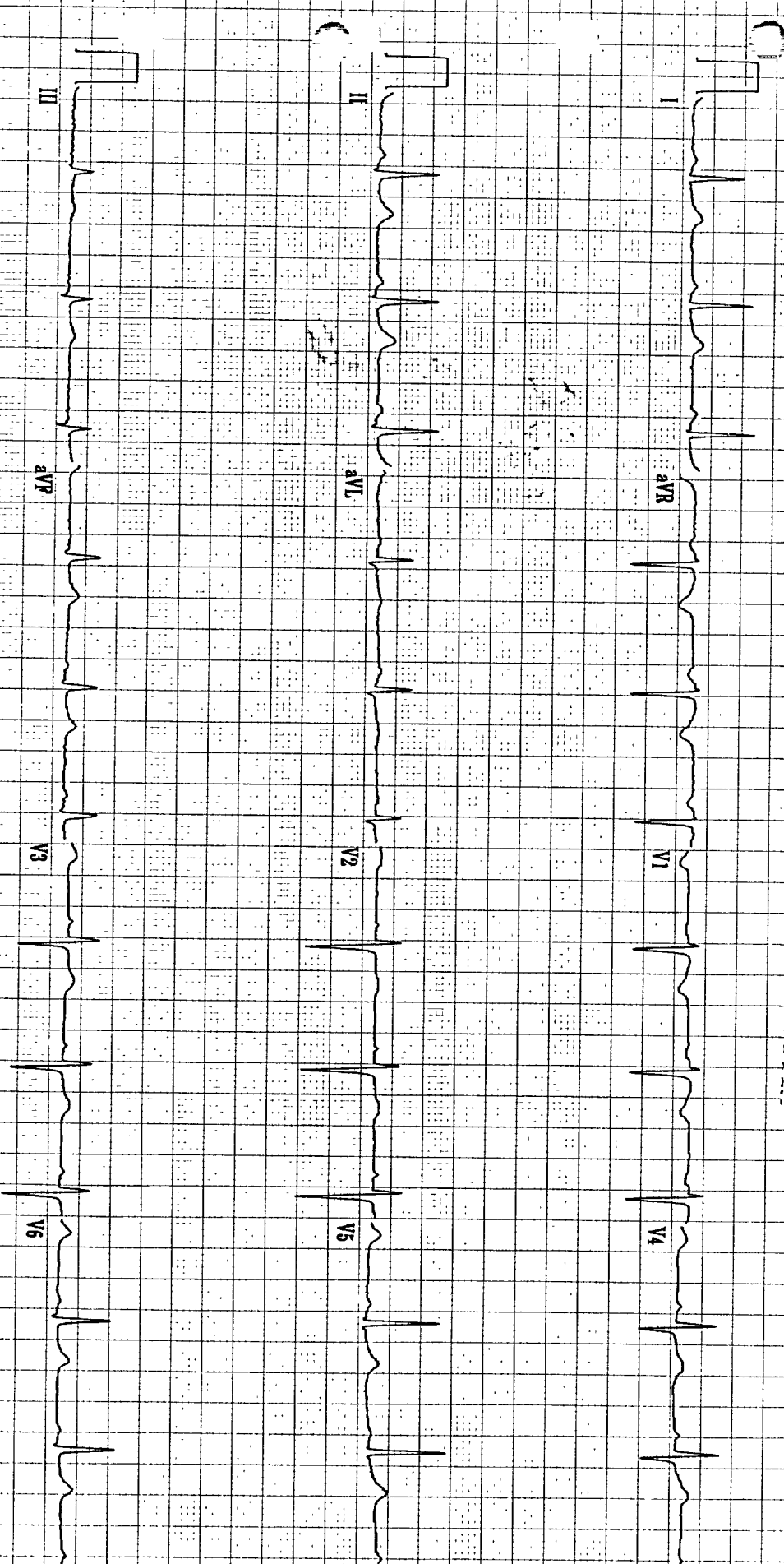
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~~SECRET~~

page of

Exhibit No: \_\_\_\_\_

000006



25mm/s 10mm/mV 40Hz 002B-04-002B 12SL-250

EID:99 EDT: 11:56 13-SEP-1998 ORDER

# ULTRASOUND REPORT

PATIENT: [REDACTED]

MED. REC. #: [REDACTED]

DOB: [REDACTED]

AGE: 56Y

DOCTOR(S): [REDACTED]

LOCATION: [REDACTED]

ESSENTIAL CLINICAL DATA:

DATE: 9/12/98

SPECIAL INSTRUCTIONS:

## RIGHT UPPER QUADRANT ULTRASOUND

Scans of the gallbladder show no gallbladder wall thickening or pericholecystic fluid. There is no cholelithiasis. The common bile duct is normal in caliber. Abdominal aorta is also normal in size. There is no aneurysmal dilatation. The visualized portions of the pancreas show no focal lesion. The pancreas is mildly prominent. The liver is echogenic, consistent with fatty infiltration. There is no free fluid within the abdomen and pelvis. The kidneys are normal.

## IMPRESSION

- 1) Negative for cholelithiasis or ductal dilatation.
- 2) Probable fatty infiltration within the liver.
- 3) Pancreas is somewhat full but without focal lesion or surrounding inflammatory change.

Dictated and Authenticated By: [REDACTED] M.D.  
Transcribed By: [REDACTED] September 13, 1998 12:46pm

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medWatch Report #13187  
Follow-Up Adverse Report. *JP*  
Thomas S. Donaldson 01-11-99  
Exhibit: 3 page 29 of 48

Medical Records

Memo Date: January 11, 1999  
Subject: F/U Adverse Report [REDACTED]  
To: Dorothy L. Olson, ASCSO  
From: Thomas S. Donaldson, CSO *TD*  
Exhibit No: page of

# Memorandum to ARMS # 13187

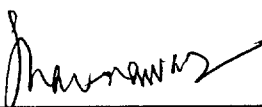
Date: 1/25/99

From: Medical Officer, Clinical Research and Review Staff, Office of Special  
Nutritionals, HFS-452

Subject: Medical Records Place in Permanent Storage.

The following types and amounts of records (more than 20 pages total) were place in permanent storage on this date because they were not considered essential for interpretation of this adverse event.

Approx Pages	Type of Records
15	Nursing notes
	Dietitian notes
	Respiratory therapy/occupational therapy/physical therapy notes
	Clergy notes
	Medication records
8	Physician's orders
8	Vital signs, fluids, input/output records
	Ventilator records
3	Hospital administrative records (e.g., insurance information, living will, etc)
1	immunization record



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